

REMARKS

Claims 1-9 were previously withdrawn. Claims 10 and 14 have been amended. Claims 11, 13, and 15 have been canceled. Claims 10, 12, 14, and 16 remain in the application. Reexamination and reconsideration of the application as amended are respectfully requested. The Examiner's comments are shown in bold.

Claim Rejections – 35 USC §112

Claims 10 and 14 are confusing because it recites the deposition of a test sample either containing human hemoglobin antigen or not containing human hemoglobin and performing test to determine the presence or absence of the hemoglobin antigen, respectively. In claim 10, for example, the test sample is recited as “containing a human hmoglobin antigen”, if this is the case, why would there be a need for an assay to detect its presence? It is recommended that to obviate the confusing, the claims be amended to recite that “a test sample *suspected* of containing heuman hemoglobin antigen” is added to the device.

The Applicant has added the words –suspected of—to both Claims 10 and 14 in accordance with the Examiner's suggestion.

Claim 13 is vague and indefinite with respect to the recitation of substituting the human hemoglobin antigen sample for a primate hemoglobin antigen sample since primate, by definite, includes human. . . .

The Applicant has canceled Claim 13.

Claim Rejections – 35 USC §102

Claims 10, 12-14 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by May et al (US 5,656,503). . . .

Regarding Claims 10 and 14:

The Applicant has narrowed Claims 10 and 14 by adding --immobilized human IgM antibodies—to the immobilized antihuman Hb antibodies at the test station. As such, the Applicant submits that Claims 10 and 14 as amended distinguish over May.

Regarding Claims 12 and 16:

Claims 12 and 16 depend from now allowable Claims 10 and 14 respectively, and are therefore also allowable.

Regarding Claim 13:

Claim 13 has been canceled.

Claim Rejections – 35 USC §103

Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Imrich et al (US 5,415,994). . . .

The Applicant has canceled Claims 11 and 15, however the subject matter of Claims 11 and 15 has been added to Claims 10 and 14 respectively, therefore the rejection of Claims 11 and 15 will be addressed in the following discussion of Claims 10 and 14.

Regarding Claims 10 and 14:

The subject matter of Claims 11 and 15 has been added to Claims 10 and 14 respectively. As such, The Applicant respectfully requests that the Examiner revisit the rejection of the subject matter formerly contained in Claims 11 and 15.

In col 5 lines 15-20 Imrich does disclose the immunoglobulin IgM. However, the discussion clearly centers on means for labeling the target analyte in the labeling zone, and not on reactions which take place in the test zone. In these lines Imrich is describing the labeling of an immunoglobins one of which could be IgM. Nowhere in this discussion does Imrich teach or suggest immobilized human IgM antibodies being disposed at the test zone.

In col 5 lines 24-27 Imrich provides a general definition of an antibody, and again provides no teaching or suggestion that immobilized human IgM antibodies are disposed at the test zone.

In col 5 lines 45-52 Imrich provide a broad description of what happens in the capture (test) zone of any assay. This discussion does specifically teach or suggest the use of immobilized human IgM antibodies at the test zone, and certainly does not teach a combination of immobilized antihuman Hb antibodies and immobilized human IgM antibodies at the test zone.

In summary, neither May nor Imrich teach or suggest a combination of immobilized antihuman Hb antibodies and immobilized human IgM antibodies being disposed at the test station.

Therefore in accordance with MPEP 2143.01 (no motivation or suggestion to modify), MPEP 2143.02 (no reasonable expectation of success), and MPEP 2143.03 (all claim limitations not taught), the Applicant submits that Claims 10 and 14 as amended are unobvious over May in view of Imrich, and should be allowable.

A fee of \$225 is included for a two month extension of time.

In view of the above, Applicant respectfully requests allowance of all the claims remaining in the application, namely Claims 10, 12, 14, and 16.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ted Masters", with a stylized flourish at the end.

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